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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/921,008	08/02/2001	Daniel G. Schmiel	6683.47US11	5027

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EXAMINER

LEWIS, RALPH A

ART UNIT PAPER NUMBER

3732

DATE MAILED: 06/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/921,008	<b>Applicant(s)</b> SCHMIEL ET AL.	
	<b>Examiner</b> Ralph A. Lewis	<b>Art Unit</b> 3732	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 21 March 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 18, 19 and 28-77 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 18, 19 and 28-77 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

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**Obvious-type Double Patenting Rejection**

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 18, 19, 50, 51, 55, 56, 57, 58 and 62 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 8 and 10 of U.S. Patent No. 6,626,905 B1 in view of Michelson (US 5,772,661)

Patented claim 8 of applicant's earlier application sets forth the "forming an implant bore," the "inserting an intervertebral implant" and the "mounting external stabilization" (i.e. "fixing a connecting rod") limitations, but fails to set forth how the vertebral bodies are distracted. Michelson, however, teaches at Figures 25-28 that it was known in the prior art at the time of applicant's invention to use a retractor tube 1000 for distracting the vertebral bodies and guiding instruments wherein the retractor tube includes paddles 1020 and 1022 and an angled distal edge. To have used the prior art Michelson intervertebral retractor in the patented '905 method would have been obvious to one of ordinary skill in the art as an obvious selection of a proper known tool

for the earlier patented procedure. In regard to the angled limitation of the implant, it is noted that applicant already patented this feature in claim 10 of 6,626,905.

In regard to the kit claims, merely providing tools used in the above claim 8/Michealson combination together in a kit so that they are readily available to the surgeon would have been obvious to one of ordinary skill in the art.

### **Rejections based on Prior Art**

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 28-33, 35, 36 and 67-77 are rejected under 35 U.S.C. 102(b) as being anticipated by MICHELSON (US 5,772,661).

In Figures 25-28 Michelson discloses an instrument guide 1000 for guiding surgical drill 250. The instrument guide comprises a tube 1002 having a distal end 1010 having an angled edge that appears (note Figure 26) to be "about" 22 degrees (or at least between "about" 10-45 degrees) to a reference line perpendicular to the longitudinal axis. The Michelson device includes diametrically opposed tapered paddles 1020 and 1022 that extend from the angled distal edge.

In regard to the newly added "adapted to rest against, and in substantial contact with a posterior surface of a human vertebra" limitation, it is noted that the Michelson

device is capable of such a use. The manner in which applicant intends for the claimed device to be used fails to impose any objectively ascertainable structural distinctions from the device disclosed by Michelson.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 33, 34 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over MICHELSON (US 5,772,661).

To the extent that Michelson fails to disclose the "about" 22 degree angle it is noted that the selection of the particularly claimed angle and the use of a conventional stop would have been obvious to one of ordinary skill in the art in constructing the Michelson device as a matter of routine.

Claims 37-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over MICHELSON (US 5,772,661) in view of MEHDIZADEH (US 6,030,390).

Mehdizadeh teaches the use of a wedge distractor plug 27 (or 11) in conjunction with a tubular instrument guide 22 that is similar to the instrument guide 1000 of

Michelson. The distractor plug 27 forms grooves in the adjacent vertebrae which help to properly position the paddle (tang) of the tubular instrument guide (see column 3, line 64 - column 4, line 6). To have provided for wedge distractor plugs for use with the Michelson instrument guide to help with the proper positioning of the instrument guide paddles as taught by Mehdizadeh would have been obvious to one of ordinary skill in the art.

Claims 42-66 are rejected under 35 U.S.C. 103(a) as being unpatentable over MICHELSON (US 5,772,661) in view of MEHDIZADEH (US 6,030,390) as applied above with respect to claims 37-41 and in further view of BRYAN (US 5,306,275).

Bryan teaches the use of conventional pedicle screws and rods (Figure 12) used in conjunction with a tubular retractor/guide instrument 132 (Figure 14). Merely substituting the Michelson retractor/guide instrument system for the Bryan retractor/guide instrument would have been obvious to one of ordinary skill in the art as would collecting the instruments together in a kit so that they would be readily available to a Surgeon.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

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For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication should be directed to **Ralph Lewis** at telephone number **(571) 272-4712**. Fax (703) 872-9306. The examiner works a compressed work schedule and is unavailable every other Friday. The examiner's supervisor, Kevin Shaver, can be reached at (571) 272-4720.

R.Lewis  
May 31, 2005



**Ralph A. Lewis**  
**Primary Examiner**  
Au3732